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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/544,632	04/06/2000	Goro Hori	506.35379CC2	9269

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EXAMINER	
KISHORE, GOLLAMUDI S	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 12/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/544,632	HORI ET AL.	
	Examiner	Art Unit	
	Gollamudi S Kishore, Ph.D	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18,35,36,38 and 42-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18, 35-36, 38 and 42-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The RCE dated 10-19-04 is acknowledged.

Claims included in the prosecution are 18, 35-36, 38 and 42-48.

Claim Rejections - 35 U.S.C. ' 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 18, 35-36, 38 and 42-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sugano (J. Nutr., 1990) or Sugano (Atherosclerosis, 1988) by themselves or in combination with Imaizumi (Agri. Biol. Chem., 53, (9), 1989 of record.

As pointed out before, the references of Sugano teach the effectiveness of soybean protein-phospholipid complexes in lowering the cholesterol levels (note the abstracts and Tables in both). The amounts of phospholipids in Sugano however, are lower than the amounts in instant invention.

Imaizumi teaches that the administration of phospholipids causes the reduction in the serum cholesterol levels (note the abstract).

It would have been obvious to alter the amounts of the phospholipids in the phospholipid-soy protein complex in Sugano, with the expectation of obtaining the best possible results, since Imaizumi teaches that phospholipids by themselves lower the cholesterol. The criticality of the enzyme-modified phospholipid is not readily apparent to the examiner; as pointed out above, the specification does not provide a definition or experiments conducted with this product.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant once again argues that both references of Sugano focus on the effect of reducing serum and liver cholesterol by an indigested high molecular fraction of soybean protein obtained after microbial protease digestion and that these references do not teach that the effect is due to the complex of protein and phospholipid. These arguments have been addressed before. First of all, as pointed out before, Sugano's compositions contain even phospholipid (see page 116, col. 2 of Atherosclerosis for example) and there is nothing in Sugano to indicate that the phospholipid is not in association with the protein (complex) and instant claims do not define the term, 'complex'. Secondly, even assuming that the phospholipid in Sugano is not in a complex form, Sugano observes cholesterol lowering effect due to the protein and small amount of phospholipid and the secondary reference of Imaizumi clearly shows that phospholipids themselves cause a reduction in the cholesterol levels. Therefore, one of ordinary skill in the art would manipulate the levels of phospholipid in Sugano to obtain

the best possible results. With regard to applicant's arguments based on enzyme modified phospholipid (page 8 of the response) :- applicant points out to Table 2 of the specification which according to applicant shows lower cholesterol amounts (group 4) compared to group 1. A careful review of the results in Table 2 (page 9 of the specification) shows no differences in cholesterol levels between groups 2-4. It is interesting to note that there are no significant differences between group 2 values wherein the rats were fed 0.8 % phospholipid in bound form and 20 % phospholipid in free form and group 3 values wherein the rats were fed 20 % bound phospholipid and 1% free cholesterol. In response applicant argues that Test groups 3 and 4 showed higher arteriosclerosis index as compared with Test groups 1 and 2 which indicates that the cholesterol metabolism in serum was improved in Test groups 3 and 4. This response however, does not address the issue that there are no significant differences between group 2 and those values in groups 3 and 4. Furthermore, no comparison has been made with 20 percent free phospholipids to indicate that bound complex behaves differently from the free phospholipids.

In response to the examiner's statement that instant claims do not define the term, 'complex', applicant argues that the term has a definite meaning in chemistry, which must be considered. The examiner agrees that this term has a specific meaning in chemistry. However, the examiner points out that the term is generic and includes covalent complexes, ionic complexes or complex formation through hydrogen bonding. Applicant has not shown that the composition in the prior art is not in a bound form

falling within these terms and that the prior art complex does not remain in a bound state after organic solvent treatment.

3. Claims 18, 35-36, 38 and 42-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirtori (Ann. Nutr. Metab. 1985) in combination with Williams (Perspectives in Biology and Medicine, 1984).

Sirtori teaches the effectiveness of lecithinated soy proteins in lowering cholesterol (note the abstract). The amount of lecithin in the complex however, is lower than the amount in instant invention.

Williams teaches the effectiveness of phospholipids in cholesterol removal (note the entire article).

It would have been obvious to alter the amounts of the phospholipids in the lecithinated soy proteins in Sirtori with the expectation of obtaining the best possible results since Williams teaches that phospholipids by themselves lower the cholesterol.

Therefore, it would have been obvious to vary the amounts of lecithin in the compositions of Sugano, 1990 and 1988 since as pointed out above, Williams teaches that phospholipids by themselves lower the cholesterol and Jenkins teaches that the level of dietary lecithin controls the effect of the source and type of protein on the lipid metabolism.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that although Sirtori teaches that low-lipid diet with total replacement of animal proteins with textured soy proteins containing 6 percent of lecithin reduces serum total cholesterol, Sirtori is silent about the effect of a

protein/phospholipid complex in which the content of bound phospholipid is from 20 % to 50 %. These arguments are not found to be persuasive since Sirtori teaches the very fact that Sirtori uses the expression lecithinated soy proteins indicates that lecithin is associated with the protein and as pointed out above, instant claims do not recite the nature of instant complex. Furthermore, as discussed above, a review of the results in Table 2 of the specification indicates no significant differences between group 2 values wherein the rats were fed 0.8 % phospholipid in bound form and 20 % phospholipid in free form and group 3 values wherein the rats were fed 20 % bound phospholipid and 1% free cholesterol. With regard to the lower amounts of lecithin in Sirtori, the examiner points out in view of the findings of Williams that phospholipids themselves remove cholesterol, one skilled in the art would vary the phospholipid amounts with the expectation of obtaining the best possible results.

Applicant's arguments based on the declaration have been fully considered, but are not found to be persuasive. Applicant once again argues that figures 1 and 2 show the lowering of cholesterol. The examiner once again points out that these figures show no cholesterol values for soy protein by itself and lecithin by itself (controls) in order to assess the synergistic effect. As also pointed out before, the data presented in Table II of the declaration appears to show an additive effect with regard to both serum cholesterol and the liver cholesterol; as evident from the prior art, soybean protein and lecithin each by itself has the ability to lower cholesterol and therefore, an additive effect is to be expected and it is not an unexpected finding. The studies are not commensurate with the scope of the claims in terms of enzyme modified phospholipids

or lecithin. In response, applicant argues that the performed studies provide evidence, which one of ordinary skill in the art would accept as establishing unexpectedly better results for use of materials commensurate with the scope of the present claims. These arguments would have been persuasive if other results presented are unexpected. However, as pointed out above, the results appear to be additive and therefore, not unexpected. In essence, the declarations do not establish the unexpected results neither with the protein or protein hydrolysates bound to phospholipid or enzyme modified phospholipids. The rejections are maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK